



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



18 APR 2017

MEMORANDUM FOR SGVT

ATTN: CAPT ANTHONY SIDARI

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled Plasma Exchange for Refractory MDA5 myositis and ILD presented at/published to North American Young Rheumatology Investigator Forum, Destin, FL, 26 April 2017 in accordance with MDWI 41-108, has been approved and assigned local file #17162.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

| PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS | | | |
|---|---|--|--|
| 1. TO: CLINICAL RESEARCH | 2. FROM: (Author's Name, Rank, Grade, Office Symbol) Anthony Sidari, Capt, O-3, SGVT | 3. GME/GHSE STUDENT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | 4. PROTOCOL NUMBER: |
| 5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) Plasma exchange for refractory MDA5 myositis and ILD | | | |
| 6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Plasma exchange for refractory MDA5 myositis and ILD | | | |
| 7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE: | | | |
| 8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | |
| 9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | |
| 10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form. | | | |
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| <input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.) | | | |
| <input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.) | | | |
| <input checked="" type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) North American Young Rheumatology Investigator Forum, Destin, FL, 04/26/2017 | | | |
| <input checked="" type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.) North American Young Rheumatology Investigator Forum, Destin, FL, 04/26/2017 | | | |
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| 12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO ASSIGNED FILE # _____ DATE _____ | | | |
| 13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC). | | | |
| DATE 01 April 2017 | | | |
| 14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Sidari, Anthony, P, anthony.p.sidari2.mil@mail.mil | | | 15. DUTY PHONE/PAGER NUMBER 210-916-0797/210-513-7462 |
| 16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript. | | | |
| LAST NAME, FIRST NAME AND M.I. | GRADE/RANK | SQUADRON/GROUP/OFFICE SYMBOL | INSTITUTION (If not 59 MDW) |
| a. Primary/Corresponding Author Anthony Sidari, MD | Capt/O-3 | 959CSPS/959MDG/SGVT | |
| b. Katherine Lawrence-Wolff, DO | Capt/O-3 | 959CSPS/959MDG/SGVT | |
| c. Daniel Battafarano, DO | RET COL/O-6 | MCHE-ZDM-R | SAUSHEC |
| d. | | | |
| e. | | | |
| 17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | |
| I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 JP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION. | | | |
| 18. AUTHOR'S PRINTED NAME, RANK, GRADE Anthony Sidari, Capt, O-3 | 19. AUTHOR'S SIGNATURE SIDARI, ANTHONY P. 1367030140 | | 20. DATE March 27, 2017 |
| 21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Daniel F. Battafarano, DO, GP15 | 22. APPROVING AUTHORITY'S SIGNATURE BATTAFARANO DANIEL FRANCIS 1031800615 | | 23. DATE March 28, 2017 |

| PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS | | |
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| TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions. | 24. DATE RECEIVED April 18, 2017 | 25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17162 |
| 26. DATE REVIEWED April 18, 2017 | 27. DATE FORWARDED TO 502 ISG/JAC | |
| 28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. _____ <input type="checkbox"/> N/A | | |
| 29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED single subject case study with appropriate disclaimers. Approved | | |
| 30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Kupferer/GS13/Human Research Subject Protection Expert | 31. REVIEWER SIGNATURE KUPFERER KEVIN R. 1086667270 <small>Digitally signed by KUPFERER KEVIN R. 1086667270 DN: cn=US, ou=US Government, ou=DOD, ou=AF, ou=AFMRL, ou=USAF email=KUPFERER KEVIN R. 1086667270 Date: 2017.04.18 10:28:30 -0500</small> | 32. DATE April 18, 2017 |
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| 41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED Presentation is approved but not as a poster since no poster was provided. | | |
| 42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs | 43. REVIEWER SIGNATURE <small>Digitally signed by IINUMA KEVIN MITSUO 1296227613 DN: cn=US, ou=US Government, ou=DOD, ou=AF, ou=AFMRL, ou=USAF, ou=IINUMA KEVIN MITSUO 1296227613 Date: 2017.04.18 12:10:40 -0500</small> | 44. DATE April 18, 2017 |
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| 45. DATE RECEIVED | 46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE | |
| 47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED | | |
| 48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER | 49. REVIEWER SIGNATURE | 50. DATE |

Sidari CCR Abstract Rough Drafts

Title: Plasma exchange for refractory MDA5 myositis and ILD

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Disclosure:

I have no financial disclosures. "The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Air Force, the Department of the Army or the Department of Defense or the U.S. Government."

Introduction:

MDA5 antibody associated idiopathic inflammatory myopathy (IIM) is associated with an increased risk for development of interstitial lung disease (ILD), may be more resistant to corticosteroid treatment and is often rapidly progressive. Treatment of IIM-associated ILD varies with use of corticosteroids, DMARDs, and biologic treatments. Plasmapheresis may effectively treat systemic disease by removal of auto-antibodies, immune complexes and various cytokines. We present a case of refractory myositis with significant improvement after initiation of plasma exchange.

Case Description:

A 55 year old African American male with history of anti-MDA5 dermatomyositis complicated by ILD on tacrolimus 4mg twice daily, prednisone 30mg daily and monthly intravenous immune globulin presented acutely with severe dyspnea, dysphagia, odynophagia and severe weakness while undergoing prednisone taper. He was admitted to the ICU tachypneic (22 resp/min), tachycardic (105 bpm), normotensive and afebrile. Laboratory assessment revealed creatine kinase (CK) of 500 IU/L, ESR 89 mm/hr, CRP 1.2 mg/dl and ferritin 2590 ng/ml. Tacrolimus trough was 10.5 ng/ml. Blood gas analysis demonstrated pH 7.46, with CO₂ 32.9 mmHg and HCO₃ 22.8 mmol/L.

Bronchoscopy demonstrated tracheobronchitis with ulcerations, and he received acyclovir for empiric treatment of herpes simplex tracheobronchitis. Endoscopy revealed esophagitis and gastritis, and the patient was treated empirically for candida esophagitis.

After initiation of empiric infectious treatment, pulse dose methylprednisolone was administered (1 gram IV daily x3) followed by prednisone 1mg/kg daily. Tacrolimus was continued. The patient continued to have unwavering symptoms with respiratory distress. A five day course of plasmapheresis was initiated on hospital day eight. Subsequently his respiratory acid-base imbalance improved with normalization of the pH, CO₂ and HCO₃ by hospital day 17. On hospital day 21, his CK had decreased to 63 IU/L and he was discharged.

Discussion:

Plasma exchange currently carries a grade IV recommendation in treatment of IIM. Our patient received robust immunosuppressive therapy alongside empiric infectious treatment, and plasma exchange was attempted as a last resort effort to halt rapid disease progression. Following plasma exchange, the patient had improvement of hypocarbic respiratory alkalosis and reversal of myositis with resolution of dysphagia/odynophagia and normalization of peripheral muscle strength.

Conclusion:

We present a case of anti-MDA5 dermatomyositis with severe ILD refractory to IV methylprednisolone treatment, who then responded dramatically to plasma exchange. Our patient's response to plasma exchange suggests a potential pathogenic role of the MDA5 antibody. In other similar cases of MDA5 polymyositis refractory to standard therapy, plasma exchange may be strongly considered.

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